



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mark A. Christopherson

Docket: P-9126

Serial No.: 09/776,265

Group Art: 3736

Filed: February 2, 2001

Examiner: David J. McCrosky

Title: INFORMATION REMOTE MONITOR (IRM) MEDICAL DEVICE

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#26
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9/9/03

APPLICANT'S BRIEF ON APPEAL

Commissioner for Patents and Trademarks
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Applicants re-submit this Brief on Appeal, originally filed April 29, 2003 in support of applicants' appeal from the rejection of the claims by the Examiner in the final Office Action mailed August 2, 2002, in response to the Examiner's phone message of August 25, 2003 that the brief failed to treat each issue under a separate heading in the Arguments section. The Appeal Brief is submitted in triplicate as required by 37 C.F.R. §1.192 and Applicants hereby authorize any fees that are due in the submission of this Brief to be charged to Deposit Account No. 13-2546.

I. REAL PARTY IN INTEREST

The real party in interest is Medtronic, Inc., by way of an assignment from the above-captioned inventor(s) recorded in the U.S. Patent and Trademark Office at Reel 011954, Frame 0171 on June 28, 2001.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals and/or interferences, which will directly affect or be directly affected by or have a bearing on the Board's decision in this pending appeal.

III. STATUS OF THE CLAIMS

The present application was originally filed with claims 1-7. Claims 1-7 were cancelled and claims 8-22 were submitted in the "Amendment in Response to Office Action Dated February 26, 2002" filed on June 3, 2002. Claims 8-22 were rejected in the Final Office Action of August 7, 2002.

IV. STATUS OF AMENDMENTS

There are no unentered amendments.

V. SUMMARY OF INVENTION

The present invention is directed to a medical data transfer system that interfaces an implantable medical device (10) with a remote center using an information remote monitor (20) that is operable to establish wireless communication with the implantable medical device. An external pressure reference (13) obtains barometric pressure data. A software module resident on the information remote monitor accesses implantable medical device cardiac pressure data, downloads barometric pressure data from the external pressure reference, and combines the data to produce corrected cardiac pressure data based on the barometric pressure data. A communication link between the information remote monitor and a remote center is established to transfer corrected cardiac pressure data.

The information remote monitor (20) has a housing with a back panel (40) and a front panel (44). The top of the housing provides a slot (54) for installation of the external pressure reference (13) during download of barometric pressure data. The back panel (40) is provided with support cradles (50) to securely stow a detached antenna (18) when not in use. The back panel further includes a power panel (60) comprising a power cord attachment (62), a serial data port (64), a telephone jack (66), and a dialing sequence switch (68). The front panel has a user interface panel (48) comprising a power indicator, a first indicator of data download from the external

pressure reference, and a second indicator of data transfer to the remote center. In operation, the information remote monitor simultaneously downloads data from the external pressure reference and data from the implantable medical device.

VI. ISSUES

1. Whether claims 8-10, 12, 13, 16, 17, 19-21 and 22 are unpatentable under 35 USC §103 as being obvious from Halperin (U.S. Patent No. 5,810,735) in view of Krichen (U.S. Patent No. 6,250,309).
2. Whether claim 11 is unpatentable under 35 USC §103 as being obvious from Halperin (U.S. Patent No. 5,810,735) in view of Krichen (U.S. Patent No. 6,250,309), and further in view of Schroepel (U.S. Patent No. 5,749,900).
3. Whether claim 14 is unpatentable under 35 USC §103 as being obvious from Halperin (U.S. Patent No. 5,810,735) in view of Krichen (U.S. Patent No. 6,250,309), and further in view of McKinnon (U.S. Patent No. 6,190,326).
4. Whether claim 15 is unpatentable under 35 USC §103 as being obvious from Halperin (U.S. Patent No. 5,810,735) in view of Krichen (U.S. Patent No. 6,250,309), and further in view of Winkler (U.S. Patent No. 5,345,362).
5. Whether claim 18 is unpatentable under 35 USC §103 as being obvious from Halperin (U.S. Patent No. 5,810,735) in view of Krichen (U.S. Patent No. 6,250,309), and further in view of Kumar (U.S. Patent No. 6,416,471).

VII. GROUPING OF CLAIMS

For purposes of this appeal, the claims 8-22 have been grouped together due to the common basis for rejection concerning Halperin in view of Krichen.

VIII. ARGUMENT

1. Rejection of claims 8-10, 12, 13, 16, 17, 19-21 and 22 under 35 USC §103 as being obvious from Halperin (U.S. Patent No. 5,810,735) in view of Krichen (U.S. Patent No. 6,250,309).

A. There is no suggestion to combine Halperin and Krichen so as to arrive at the claimed subject matter, as a whole, of Claim 8

The basis for the final rejection was that Halperin discloses the use of an external barometric pressure sensor used in combination with an absolute pressure measurement obtained by an implanted cardiac pressure sensor. The data is telemetered to a programmer. Halperin, however, fails to disclose a communication link between an information remote monitor (programmer) and a remote center over which corrected cardiac pressure data is transferred. Krichen is relied upon as teaching a system of transferring information from an implanted medical device to a remote center.

Krichen is also characterized in the final rejection as disclosing “an IMD having a pressure sensor.” The examiner cites to column 6, lines 17-19. What is described there is an IMD that can operate in a “rate responsive” mode. As described earlier at column 4, lines 8-20, the IMD is shown as having an activity sensor providing an output that varies as a function of a measured parameter related to the patient’s metabolic requirements. The sensor can be an accelerometer or it can be a sensor that measures the rate of change in right ventricular pressure. An increase in pacing rate is linked to an increase in right ventricular pressure rate of change. Krichen is in contrast to the IMD specified in claim 8, which has a hemodynamic monitor providing cardiac pressure data. An activity sensor as described in Krichen does not provide a measurement of cardiac pressure data.

Also, Krichen discloses that only data obtained by a programmer from an IMD is formatted for communication to a remote center. Halperin on the other hand involves not only obtaining data from an IMD but also combining it with an external data source (pressure sensor) for local use in modification of the operating parameters of the IMD. There is no suggestion in Krichen that IMD data combined with an external data source, as present in Halperin, is to be communicated to a remote center.

The controlling statutory provision of 35 USC §103 requires that the differences between the subject matter sought to be patented and the prior art are such that the subject matter "*as a whole would have been obvious*" to a person having ordinary skill in the art. The legal standard applied in the rejection however only finds that one of ordinary skill in the art would have found it obvious *to modify* Halperin with the communication system of Krichen. Thus, the rejection applies an incorrect legal standard.

Even if Halperin could be so modified, that finding nevertheless does not meet the requirement that it would have been obvious to make the claimed combination *as a whole*. For such a finding, there must be some suggestion or motivation for combining the references. *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308 (Fed. Cir. 1999); *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999). Nowhere does the rejection identify any suggestion to combine the references. The rejection only finds that Halperin could be modified to provide information at a remote location. The Federal Circuit in *In re Dembiczak* reversed the Board's decision of obviousness for a failure, as here, to cite specific information in the prior art that would suggest the combination of the prior art references. *Id.* at 1000.

The examiner appears to place reliance on the level of skill in the art as the source of the motivation. As instructed by the Federal Circuit in *Al-SiteCorp. V. VSI Int'l, Inc.*, 174 F.3d 1308 (Fed. Cir. 1999), it is unlikely that the necessary suggestion can be provided by a showing of the level of ordinary skill in the art because to imbue one skilled in the art with the invention is to fall victim to hindsight reconstruction.

Here, because the Halperin and Krichen references concern different types of data, there is a clear inability to cite to any specific information in Krichen that would suggest modifying Halperin in a manner that would allegedly result in the claimed combination. Absent such a suggestion, a decision of obviousness cannot stand as a matter of law and the rejection is in error.

- B. The examiner's alleged "desireability" in the prior art to transfer data from an implantable medical device to a remote location for further review does not satisfy the requirement a suggestion to combine Halperin and Krichen

Following Applicant's challenge to the Final Rejection as being improper for failing to identify any suggestion to combine the references, in a subsequent Advisory Action, the argument was made that the required suggestion to combine comes from the references themselves. The argument further advanced a view that the prior art in fact expresses the "desireability" of transferring data from an implantable medical device to a remote location for further review. The alleged support for the suggestion to combine and such "desireability" was said to come from Krichen at col. 11, lines 57-59 and lines 60-67. In Krichen, the only desire that is indicated is one for an information format which can easily be interpreted and manipulated to allow for interpretation of data received as a "data dump" from an implanted medical device. Thus, the desire and any "suggestion" provided by Krichen is expressly restricted to a situation where an implantable medical device "dumps" its information to a programmer (col. 1, lines 46-53).

The device of Halperin does not involve a programmer that merely obtains a "data dump" from an implantable medical device. The uniqueness of the data generated in Halperin stands in contrast to a "data dump." This distinction is underscored by the very portion in Halperin cited by the Advisory Action as further supporting a suggestion to combine the references (i.e., col. 6, lines 22-28). There, what is identified is "a set of data" that is generated which "may be interpreted by another computerized machine downstream." The set of data is not obtained by an information "dump."

The reach of the teaching of Krichen in regard to what is termed in the Advisory Action as "a connection which facilitates transfer of info between programmer and computer" does not extend to information resident on a programmer that is not a "data

dump” of implantable medical device information. The Advisory Action fails to grasp the limited focus of Krichen and generalizes what Krichen contemplates in terms of communicating data from an implantable medical device to a remote location. The overly broad generalization of Krichen results from an attempted hindsight reconstruction of the claimed invention and at best what amounts to a mere verbal correspondence of the prior art to claim 8.

2. Rejection of claim 11 under 35 USC §103 as being obvious from Halperin (U.S. Patent No. 5,810,735) in view of Krichen (U.S. Patent No. 6,250,309), and further in view of Schroepfel (U.S. Patent No. 5,749,900).

Schroepfel teaches a cardiac stimulator responsive to heart rate for evaluating heart rate variability in order to forecast a cardiac event, and includes various therapy regimes, which may include an increased level of diagnostic data collection depending upon the corresponding cardiac condition of the patient. Neither Schroepfel, and for reasons set forth above, Halperin nor Krichen, alone or in combination, teach or suggest a communication link between the information remote monitor and a remote center transferring corrected cardiac pressure data. Therefore, it is respectfully asserted that the rejection of claim 11 is improper.

3. Rejection of claim 14 is unpatentable under 35 USC §103 as being obvious from Halperin (U.S. Patent No. 5,810,735) in view of Krichen (U.S. Patent No. 6,250,309), and further in view of McKinnon (U.S. Patent No. 6,190,326).

McKinnon teaches a system for collecting patient respiratory information that includes a mouthpiece unit having sensors that sense parameters of a patient's breath when the patient blows in the mouthpiece and a base unit that receives and processes the information from the mouthpiece unit and store it in chronological fashion. When the mouthpiece unit is inserted within the base unit, the base unit reads identification information from the mouthpiece unit and stores all measurement information in association therewith. Neither McKinnon, and for reasons set forth above,

Halperin nor Krichen, alone or in combination, teach or suggest a communication link between the information remote monitor and a remote center transferring corrected cardiac pressure data. Therefore, it is respectfully asserted that the rejection of claim 14 is improper.

4. Rejection of claim 15 under 35 USC §103 as being obvious from Halperin (U.S. Patent No. 5,810,735) in view of Krichen (U.S. Patent No. 6,250,309), and further in view of Winkler (U.S. Patent No. 5,345,362).

Winkler teaches a portable computer apparatus having a dual-pivot articulating display screen capable of being adjusted to a plurality of different viewing angles as desired. Neither Winkler, and for reasons set forth above, Halperin nor Krichen, alone or in combination, teach or suggest a communication link between the information remote monitor and a remote center transferring corrected cardiac pressure data. Therefore, it is respectfully asserted that the rejection of claim 15 is improper.

5. Rejection of claim 18 under 35 USC §103 as being obvious from Halperin (U.S. Patent No. 5,810,735) in view of Krichen (U.S. Patent No. 6,250,309), and further in view of Kumar (U.S. Patent No. 6,416,471).

Kumar teaches a small signal transfer unit that can either be worn by the patient, e.g., on his or her belt, or positioned nearby that receives data from a sensor band, which it then forwards by e.g., radio transmission to a base station that can be located up to 60 meters away. The base station receives data transmissions from the signal transfer unit and is designed to connect to conventional phone lines for transferring the collected data to a remote monitoring station. The base station may also capture additional clinical data, such as blood pressure data, and to perform data checks. Neither Kumar, and for reasons set forth above, Halperin nor Krichen, alone or in combination, teach or suggest a communication link between the information remote monitor and a remote center transferring corrected

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cardiac pressure data. Therefore, it is respectfully asserted that the rejection of claim 18 is improper.


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IX. CONCLUSION

The Examiner has erred in rejecting claims 8-22. It is respectfully requested that the rejection of claims 8-22 be reversed and a notice of allowance be issued.

Respectfully Submitted,

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APPENDIX A

CLAIMS INVOLVED ON APPEAL

8. A medical data transfer system interfacing an implantable medical device comprising a hemodynamic monitor providing cardiac pressure data with a remote center, comprising:
 - an information remote monitor operable to establish wireless communication with an implantable medical device;
 - an external pressure reference operable to obtain barometric pressure data;
 - a software module resident on the information remote monitor to access implantable medical device cardiac pressure data, download barometric pressure data from the external pressure reference, and combine the data to produce corrected cardiac pressure data based on the barometric pressure data; and
 - a communication link between the information remote monitor and a remote center transferring corrected cardiac pressure data.
9. The system of claim 8 further comprising a personal computer interfaced between the information remote monitor and the remote center.
10. The system of claim 8 wherein the communication link comprises a modem and a transmission medium.
11. The system of claim 8 wherein the implantable medical device executes high resolution data collection upon occurrence of a trigger event selected from a group consisting of a bradycardia trigger, a tachycardia trigger, and a patient activated trigger.
12. The system of claim 8 wherein wireless communication between the information remote monitor and the implantable medical device is bi-directional.

13. The system of claim 8 wherein the information remote monitor comprises a housing and a detached antenna.

14. The system of claim 13 wherein the housing comprises a back panel, a front panel and a top structure having a slot for installation of the external pressure reference during download of barometric pressure data.

15. The system of claim 13 wherein the housing comprises a back panel having cradles to support the antenna in a stowed position.

16. The system of claim 13 wherein the housing comprises a back panel having a power panel comprising a power cord attachment, a serial data port, and a telephone jack.

17. The system of claim 16 further comprising a dialing sequence switch.

18. The system of claim 13 wherein the housing comprises a front panel having a user interface panel comprising a power indicator, a first indicator of data download from the external pressure reference, and a second indicator of data transfer to the remote center.

19. The system of claim 8 wherein the information remote monitor simultaneously downloads data from the external pressure reference and data from the implantable medical device.

20. The system of claim 8 further comprising a personal computer connected to the information remote monitor to control the information remote monitor in programming the implantable medical device.

21. The system of claim 8 wherein the information remote monitor includes an internal modem to dial the remote center and transfer data over the communication link in a protocol selected from a group consisting of FTP, PPP and TC/PIP protocols.

22. The system of claim 8 wherein the communication link comprises a transfer medium selected from a group consisting of a phone line, a cable modem, an ISD line, and a wireless data transmission system.